

MAR - 9 2004

K032459

Attachment IV

510(k) Summary

Submitter: Sciton, Inc.

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Contact Person: Jay M. Patel, Director of Regulatory Affairs

Date Prepared: August 1, 2003

Device Trade Name: Profile 1320 Laser System

Common Name: Nd:YAG Laser System

Classification Name: Laser Surgical Instrument, 21 CFR 878.4810.

Legally Marketed Predicate Device: Profile 1320 Laser System (K022466, K022381)
CoolTouch Nd:YAG Laser System (K031184, K030453
K022817, K014035 and K012982)
Candela Smoothbeam Laser System (K022884, K014128
and K013825)

Description of Profile 1320 Laser System: Profile 1320 Laser System is an Nd:YAG laser producing emission at a wavelength of 1320 nm. It consists of a laser console, internal computer, control panel and display, an optical delivery system comprised of an articulated arm and a handpiece or scanner with cooling capability, and a footswitch.

Intended Use: The Sciton, Inc. Profile 1320 Laser is intended for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation, with hemostasis of soft tissue. It is indicated for the treatment of fine lines and wrinkles. It is also indicated for the treatment of back acne and atrophic acne scars.

Rationale for Substantial Equivalence: The Profile 1320 Laser System shares the same indications for use, similar design features (including wavelength, laser medium, power supply, cooling and control system), functional features (including power output, repetition rate, energy, spot size and fluence), and

	<p>is therefore substantially equivalent to the above legally marketed predicate devices.</p>
Safety and Effectiveness Information	<p>The indications for use are based upon the indications for use for predicate systems. Technologically, the Profile 1320 Laser System is substantially equivalent to the listed predicate devices. Therefore, the risks and benefits for the Profile 1320 Laser System are comparable to the predicate devices.</p>
Conclusion	<p>The Profile 1320 shares similar indications for use, design features, and similar functional features as, and therefore is substantially equivalent to, the currently marketed predicate devices.</p>

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

MAR - 9 2004

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

Mr. Jay M. Patel
Director of Regulatory Affairs
Sciton, Inc.
845 Commercial Street
Palo Alto, California 94303

Re: K032459

Trade/Device Name: Profile 1320 Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: December 10, 2003
Received: December 12, 2003

Dear Mr. Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

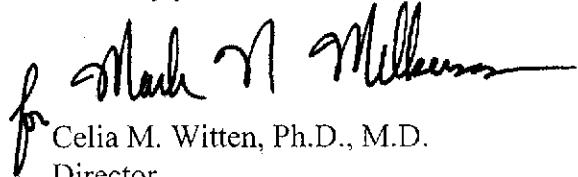
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative

and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Attachment III

Statement of Indications for Use

510(k) Number (if known): K032459

Device Name: Profile 1320 Laser System

Indications for Use:

The Sciton, Inc. Profile 1320 Laser is intended for use in general surgery and dermatology for the incision, excision, ablation, vaporization, coagulation, with hemostasis of soft tissue.

It is indicated for the treatment of fine lines and wrinkles. It is also indicated for the treatment of back acne and atrophic acne scars.

(The indications for use in this paragraph are new per this 510k.)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21CFR801)

OR Over-The-Counter Use
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K032459